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| **National CAR T Clinical Panel for lymphoma Application Form:**  **Tecartus for treating mantle cell lymphoma (MCL) in adults previously treated with two or more lines of systemic therapy**  Forms must be submitted to [england.nccp@nhs.net](mailto:england.nccp@nhs.net) by 5pm each Friday for consideration at the NCCP lymphoma on the following Tuesday |

**NOTES FOR COMPLETION**

Section A

* This section must be completed by the treating consultant at the patient’s local hospital and should provide a comprehensive history of the patient’s treatment to date
* Reviewing centres should countersign this section to confirm the patient is eligible for consideration for CAR T therapy

SECTION B

* This section must be completed by a CAR T centre following a consultation with the patient

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| **SECTION A** | |
| **Patient details** | |
| Name |  |
| NHS No |  |
| Age | *Must be 18 years or older on date of approval by National CAR T Clinical Panel* |
| **Clinical background** | |
| Referral details | Consultant name:  Hospital:  Date of referral for consideration for CAR T: |
| 1. Confirmed histological diagnosis | *Delete as appropriate*   * Mantle cell lymphoma with cyclin D1 overexpression * Mantle cell lymphoma with the presence of the translocation t(11:14) |
| 1. Please provide an overview of the patient’s previous treatment | *(please include number of lines of treatment, regimen details and date of last therapy)*  *Note:*   * *Radiotherapy is not counted as a line of treatment* * *Corticosteroids alone are not counted as a line of treatment* * *Stem cell transplant is not counted as a line of treatment when used as consolidation of a response to first or second line therapy*   ***Please provide a narrative of the patient’s treatment to date:***   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Treatment regimen | Start date | Stop date | Number of cycles | Response to treatment | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |   *If current treatment is ongoing write ‘ongoing’ under ‘response to treatment’* |
| 1. The histological diagnosis of MCL has been either made by or reviewed and confirmed by a designated lymphoma stem cell transplant centre | |  |  |  | | --- | --- | --- | | Biopsy number | Date performed | Conclusion from report | |  |  |  | | 1st |  |  | | 2nd |  |  | | 3rd |  |  | | Most recent (if not one of above) |  |  | |
| 1. I confirm that the patient fulfils one of the following clinical scenarios relating to the definition of relapsed or refractory lymphoma | **Refractory disease is defined as either progressive disease as the best response to the last line of systemic therapy or stable disease as the best response after at least 2 cycles of the last line of therapy with stable disease duration lasting no longer than 6 months from the last dose of the last line of systemic therapy.**  **Relapsed disease is defined as disease that responded partially or completely to the last line of therapy and has since progressed.**  **Progressive disease must be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans. Progressive disease cannot be defined on just an increased SUV on a PET scan; in such a circumstance, RECIST version 1.1 criteria for progressive disease must be met.**  **Neither radiotherapy nor steroids can be counted as a line of therapy.**  The patient (delete as appropriate):   * has received 2 or more lines of systemic therapy for MCL and was refractory to the last line of systemic therapy OR * has received 2 or more lines of systemic therapy for MCL and relapsed after the last line of systemic therapy |
| 1. I confirm that that the patient has been previously treated for MCL with one of the following cytotoxic chemotherapy regimens: an anthracycline-containing regimen or a bendamustine-containing regimen or a regimen containing high dose cytarabine with or without cisplatin/carboplatin | The patient (delete as appropriate):   * has been previously treated with an anthracycline-containing regimen OR * has been previously treated with a bendamustine-containing regimen OR * has been previously treated with a high dose cytarabine-containing regimen with or without cisplatin/carboplatin |
| 1. I confirm that that the patient has been previously treated for MCL with a BTK inhibitor (such as ibrutinib or acalabrutinib) and that the patient progressed either during treatment or following discontinuation of the BTK inhibitor. | The patient (delete as appropriate):   * has been previously treated with ibrutinib OR * has been previously treated with acalabrutinib OR * has been previously treated with another BTK inhibitor |
| 1. I confirm that the patient has been previously treated with at least one anti-CD20 monoclonal antibody unless there is clear documentation of the determination of CD20 negative disease |  |
| 1. Please provide details on the patient’s prior treatment with stem cell transplantation (SCT) | The patient (delete as appropriate):   * has not had SCT * has had autologous SCT * has had allogeneic SCT |
| 1. I confirm that either the patient has not previously been treated with an anti-CD19 antibody-drug conjugate or if previously treated with an anti-CD19 antibody-drug conjugate that a biopsy of the relapsed/refractory disease has been done and has been shown to be CD19 positive |  |
| 1. I confirm that the patient does not have known active CNS involvement by the lymphoma |  |
| 1. I confirm that the patient has an ECOG performance score of 0 or 1 | *Please select from the options below*   |  |  |  | | --- | --- | --- | | **Grade** | **ECOG performance status** |  | | 0 | Fully active, able to carry on all pre-disease performance without restriction |  | | 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |  | | 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours |  | | 3 | Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours |  | | 4 | Completely disabled; cannot carry on any selfcare; totally confined to bed or chair |  | |
| 1. Please provide details of any active co-morbidities | Please list all active co-morbidities   |  |  | | --- | --- | | *Active co-morbidity* | *Severity score (see score under table)* | |  |  | |  |  | |  |  | |  |  |   *1: Current mild problem or past significant problem.  2: Moderate disability or morbidity and/or requires therapy.  3: Severe problem and/or constant and significant disability and/or hard to control chronic problems.  4: Extremely severe problem and/or immediate treatment required and/or organ failure and/or severe functional impairment.* |
| **Allogeneic centre review (if applicable)** | |
| 1. I confirm that the patient has sufficient end organ function to tolerate treatment with CAR T cell therapy |  |
| 1. I confirm that the patient has either had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial. | (delete as appropriate)   * No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or** * Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial |
| 1. I confirm that this patient should be referred to a CAR T centre for consideration for CAR T Therapy | *Please specify*   * Patient is clearly eligible and has been forwarded to a CAR T centre for consideration without review. * Patient reviewed and deemed eligible by autograft centre clinician. Eligibility required confirmation by CAR T centre   Name:  Signature:  Hospital:  Date: |

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| **SECTION B** | |
| **Details of consultation at CAR T Centre** | |
| Date of consultation |  |
| Consultant seen |  |
| CAR T Centre |  |
| 1. I confirm that the patient has an ECOG performance score of 0 or 1 | |  |  |  | | --- | --- | --- | | **Grade** | **ECOG performance status** |  | | 0 | Fully active, able to carry on all pre-disease performance without restriction |  | | 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |  | | 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours |  | | 3 | Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours |  | | 4 | Completely disabled; cannot carry on any selfcare; totally confined to bed or chair |  |   Please select from the below |
| 1. Prior to infusion 4 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome |  |
| **Available clinical trials** | |
| 1. List the clinical trials available to this patient |  |
| **CAR T centre endorsement** | |
| I confirm that I endorse this application for treatment | Name:  Position: |